The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Appropriations

BILL:	CS/CS/SB 1094
INTRODUCER:	Appropriations Committee; Health Policy Committee; and Senator Diaz
SUBJECT:	The Practice of Pharmacy
DATE:	March 4, 2020 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Fav/CS**
2.	Howard	Kidd	AHS	**Recommend: Favorable**
3.	Howard	Kynoch	AP	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1094 expands the scope of practice of professional pharmacists to include:

- Ordering and evaluating any laboratory or clinical testing;
- Conducting patient assessments;
- Modifying, discontinuing, or administering medicinal drugs pursuant to section 465.0125, Florida Statutes, by a consultant pharmacist; and
- Conducting "other pharmaceutical services," which includes reviewing and making recommendations regarding the patient's drug therapy and health care status to a patient's prescribing physician, podiatrist, or dentist regarding the patient's drug therapy and health care status, and initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement.

The bill authorizes a consultant pharmacist to enter into a written collaborative practice agreement (CPA) with a health care facility medical director, or Florida-licensed physician, podiatrist, or dentist, who is authorized to prescribe medication. The bill also expands the locations where, under a CPA, a consultant pharmacist may offer his or her services, to include:

- Ambulatory surgical center;
- Inpatient hospice;
- Hospital;
- Alcohol or chemical dependency treatment center;
- Ambulatory care center; or

- Nursing home or nursing home within a continuing care facility.

A consultant pharmacist may only provide services to the patients of the health care practitioner with whom the consultant pharmacist has a written collaborative practice agreement. The bill requires both the consultant pharmacist and health care practitioner to maintain a copy of the collaborative agreement and make it available upon request or during an inspection. The bill also requires the consultant pharmacist to maintain all drug, patient care, and quality assurance records.

The bill adds provisions for pharmacists who are certified by the Board of Medicine to provide chronic health condition services under a collaborative pharmacy practice agreement:
- Requiring the terms and conditions of the agreement be appropriate to the training of the pharmacist and the scope of practice of the physician;
- Requiring notification to the Board of Pharmacy (Board) upon practicing under the agreement;
- Requiring maintenance of patient records for a certain timeframe;
- Prohibiting certain actions relating to the agreement;
- Requiring specific continuing education for a pharmacist practicing under the agreement; and
- Requiring the Board of Medicine in consultation with the Board of Osteopathic Medicine and the Board to adopt rules.

The bill requires a licensed pharmacist, authorized under a collaborative pharmacy practice agreement, to report any diagnoses or suspicions of the existence of a disease of public health significance immediately to the Department of Health (department).

The bill has an insignificant fiscal impact on the department that can be absorbed within existing resources.

The bill provides an effective date of July 1, 2020.

II. Present Situation:

Pharmacist Licensure

Pharmacy is the third largest health profession behind nursing and medicine.[1] The Board of Pharmacy (Board), in conjunction with the Department of Health (department), regulates the practice of pharmacists pursuant to ch. 465, F.S.[2] To be licensed as a pharmacist, a person must:[3]
- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;[4]

[1] American Association of Colleges of Pharmacy, *About AACP*, *available at* https://www.aacp.org/about-aacp (last visited Feb. 6, 2020).
[2] Sections 465.004 and 465.005, F.S.
[3] Section 465.007, F.S. The department may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.
[4] If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy

- Have completed a Board-approved internship; and
- Successfully complete the Board-approved examination.

A pharmacist must complete at least 30 hours of Board-approved continuing education during each biennial renewal period.[5] Pharmacists who are certified to administer vaccines or epinephrine auto-injections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine auto-injections as a part of the biennial licensure renewal.[6] Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education for biennial licensure renewal.[7]

Pharmacist Scope of Practice

In Florida, the practice of the profession of pharmacy includes:[8]

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of any medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;[9]
- Administering epinephrine autoinjections;[10] and
- Administering antipsychotic medications by injection.[11]

A pharmacist may not alter a prescriber's directions, diagnose or treat any disease, initiate any drug therapy, or practice medicine or osteopathic medicine, unless permitted by law.[12]

Pharmacists may order and dispense drugs that are included in a formulary developed by a committee composed of members of the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Pharmacy.[13] The formulary may only include:[14]

- Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the U.S. Food and Drug Administration (FDA);

Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a department-licensed pharmacist.

[5] Section 465.009, F.S.
[6] Section 465.009(6), F.S.
[7] Section 465.1893, F.S.
[8] Section 465.003(13), F.S.
[9] *See* s. 465.189, F.S.
[10] *Id.*
[11] Section 465.1893, F.S.
[12] Section 465.003(13), F.S.
[13] Section 465.186, F.S.
[14] *Id.*

- Any medicinal drug recommended by the FDA Advisory Panel for transfer to over-the-counter status pending approval by the FDA;
- Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination;
- Any medicinal drug containing fluoride in any strength;
- Any medicinal drug containing lindane in any strength;
- Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program; and
- Any topical anti-infectives excluding eye and ear topical anti-infectives.

A pharmacist may order, within his or her professional judgment, and subject to the stated following stated conditions:

- Certain oral analgesics for mild to moderate pain. The pharmacist may order these drugs for minor pain and menstrual cramps for patients with no history of peptic ulcer disease. The prescription is limited to a six day supply for one treatment of:
  - Magnesium salicylate/phenyltoloxamine citrate;
  - Acetylsalicylic acid (Zero order release, long acting tablets);
  - Choline salicylate and magnesium salicylate;
  - Naproxen sodium;
  - Naproxen;
  - Ibuprofen;
  - Phenazopyridine, for urinary pain; and
  - Antipyrine 5.4%, benzocaine 1.4%, glycerin, for ear pain if clinical signs or symptoms of tympanic membrane perforation are not present;
- Anti-nausea preparations;
- Certain antihistamines and decongestants;
- Certain topical antifungal/antibacterials;
- Topical anti-inflammatory preparations containing hydrocortisone not exceeding 2.5%;
- Otic antifungal/antibacterial;
- Salicylic acid 16.7% and lactic acid 16.7% in flexible collodion, to be applied to warts, except for patients under 2 years of age, and those with diabetes or impaired circulation;
- Vitamins with fluoride, excluding vitamins with folic acid in excess of 0.9 mg.;
- Medicinal drug shampoos containing Lindane for the treatment of head lice;
- Ophthalmics. Naphazoline 0.1% ophthalmic solution;
- Certain histamine H2 antagonists;
- Acne products; and
- Topical Antiviral for herpes simplex infections of the lips.[15]

[15] Fla. Admin. Code R. 64B16-27.220 (2019).

Consultant Pharmacists

A consultant pharmacist is a pharmacist who provides expert advice on the use of medications to individuals and older adults.[16] To be licensed as a consultant pharmacist, an applicant must:[17]

- Hold a license as a pharmacist that is active and in good standing;
- Successfully complete an approved consultant pharmacist course of at least 12 hours;[18] and
- Successfully complete a 40-hour period of assessment and evaluation under the supervision of a preceptor within one year of completion of an approved consultant pharmacist course.

Education and Training Requirements for Consultant Pharmacists

In addition to the training and education received as a part of a degree program in pharmacy, a consultant pharmacist is required to complete a consultant pharmacy course and a period of assessment and evaluation under the supervision of a preceptor. The Board has general rulemaking authority to adopt rules to implement the pharmacy practice act and specific authority to adopt rules related to the licensure of consultant pharmacists.[19] The Board does not have specific authority to adopt rules related to the educational requirements for consultant pharmacists. Regardless, the Board has, by rule, established the minimum educational and training requirements for licensure as a consultant pharmacist.[20]

The Board has specified the topics on which a consultant pharmacist may be trained in order to qualify for the designation. The consultant pharmacy course must provide at least 12 hours of education in the following areas:[21]

- Laws and rules including state and federal laws and regulations pertaining to health care facilities, institutional pharmacy, safe and controlled storage of alcohol and other related substances, and fire and health-hazard control;
- Policies and procedures outlining the medication system in effect and record-keeping for controlled substance control and record of usage, medication use evaluation, medication errors, statistical reports, etc.;
- Fiscal controls;
- Personnel management, including intra-professional relations pertaining to medication use and inter-professional relations with other members of the institutional health care team to develop formularies, review medication use and prescribing, and the provision of in-service training of other members of the institutional health care team;
- Professional responsibilities, including:
  - Drug information retrieval and methods of dispersal;
  - Development of pharmacy practice;

[16] American Society of Consultant Pharmacists, *What is a Senior Care Pharmacist,* available at http://www.ascp.com/page/whatisacp (last visited Feb. 6, 2020). Consultant pharmacists are often referred to as "senior care pharmacist."
[17] Fla. Admin. Code R. 64B16-26.300, (2019).
[18] Fla. Admin. Code R. 64B16-26.300, (2019) requires the course to be sponsored by an accredited college of pharmacy and approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and subject matter set forth in Fla. Adm. Code R. 64B16-26.301(2019).
[19] Section 465.005, F.S.
[20] Fla. Admin. Code R. 64B16-26.300,(2019).
[21] Fla. Admin. Code R. 64B16-26.300 and 64B16-26.301(2019).

  - Development of an IV Admixture service;
  - Procedures to enhance medication safety, including availability of equipment and techniques to prepare special dosage forms for pediatric and geriatric patients, safety of patient self-medication and control of drugs at bedside, reporting and trending adverse drug reactions, screening for potential drug interactions, and proper writing, initiating, transcribing and/or transferring patient medication orders;
  - Maintenance of drug quality and safe storage;
  - Maintenance of drug identity.
- The institutional environment, including the institution's pharmacy function and purpose, understanding the scope of service and in-patient care mission of the institution, and interdepartmental relationships important to the institutional pharmacy; and
- Nuclear pharmacy, including procurement, compounding, quality control procedures, dispensing, distribution, basic radiation protection and practices, consultation and education to the nuclear medical community, record-keeping, reporting adverse drug reactions and medication errors, and screening for potential drug interactions.

The applicant must score a passing grade on the course examination for certification of successful completion.[22]

A consultant pharmacist must successfully complete a period of assessment and evaluation, under the supervision of a qualified preceptor, within one year of completing the consultant pharmacy educational course.[23] The period of assessment and evaluation must be completed within three consecutive months and include at least 40 hours of training in the following practice areas:[24]

- Twenty-four hours on regimen review, documentation, and communication;
- Eight hours on facility review, including the ability to demonstrate areas that should be evaluated, documentation, and reporting procedures;
- Two hours on committee and reports, including the review of quarterly quality of care committee minutes and preparation and delivery of the pharmacist quarterly report;
- Two hours on policy and procedures, including preparation, review, and updating Policy and Methods;
- Two hours on principles of formulary management; and
- Two hours on professional relationships, including knowledge and interaction of facility administration and professional staff.

At least 60 percent of this training must occur on-site at an institution that holds a pharmacy permit.[25]

[22] *Id.*
[23] Fla. Admin. Code R. 64B16-26.300(3)(c)(2019).
[24] *Id.* To act as a preceptor, a person must be a consultant of record at an institutional pharmacy, have a minimum of one year experience as a consultant pharmacist of record, and be licensed, in good standing, with the board. A preceptor may not supervise more than two applicants at the same time.
[25] *Id.*

Scope of Practice

The scope of practice for a consultant pharmacist is broader than that of a pharmacist. A consultant pharmacist may order and evaluate laboratory testing in addition to the services provided by a pharmacist. For example, a consultant pharmacist can order and evaluate clinical and laboratory testing for a patient residing in a nursing home upon authorization by the medical director of the nursing home.[26] Additionally, a consultant pharmacist may order and evaluate clinical and laboratory testing for individuals under the care of a licensed home health agency, if authorized by a licensed physician, podiatrist, or dentist.[27]

Pharmacist Collaborative Practice Agreements

A collaborative practice agreement (CPA) is a formal agreement in which a licensed practitioner makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions.[28] A CPA specifies what functions beyond the pharmacist's typical scope of practice can be delegated to the pharmacist by the collaborating health care practitioner.[29] Common tasks include initiating, modifying, or discontinuing medication therapy and ordering and evaluating tests.[30]

As of May 2016, 48 states, including Florida, permit some type of collaborative practice between a pharmacist and a prescriber.[31] However, the laws and regulations of these states vary in areas such as the functions that may be authorized, the requirements for collaborative agreements, and the qualifications for participants.[32]

III. Effect of Proposed Changes:

The bill amends s. 465.003, F.S., to expand the scope of the, "practice of the profession of pharmacy," to include:

- Ordering and evaluating any laboratory or clinical testing;
- Conducting patient assessments;
- Modifying, discontinuing, or administering medicinal drugs pursuant to s. 465.0125, F.S. by a consultant pharmacist; and
- Conducting "other pharmaceutical services," which includes reviewing and making recommendations regarding the patient's drug therapy and health care status with the patient's prescribing physician, podiatrist, or dentist regarding the patient's drug therapy and

[26] Section 465.0125(1), F.S.
[27] Section 465.0125(2), F.S. To qualify to order and evaluate such testing, the consultant pharmacist or doctor of pharmacy must complete 3 hours of board-approved training, related to laboratory and clinical testing.
[28] U.S. Center for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention, *Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists*, (2013), *available at* https://www.cdc.gov/dhdsp/pubs/docs/translational_tools_pharmacists.pdf (last visited Feb. 7, 2020).
[29] U.S. Center for Disease Control and Prevention, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*, (2017) *available at* https://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf (last visited Feb. 7, 2020).
[30] *Supra* note 28.
[31] *Supra* note 29.
[32] *Id.*

health care status, and initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement.

The bill amends s. 465.0125, F.S., authorizing a consultant pharmacist to enter into a written CPA with a health care facility medical director, or a Florida-licensed allopathic physician, osteopathic physician, podiatric physician, or dentist, who is authorized to prescribe medication, to provide medication management services, which may include:

- Order and evaluate any laboratory or clinical tests to promote and evaluate patient health and wellness, and monitor drug therapy and treatment outcomes;
- Conduct patient assessments as appropriate to evaluate and monitor drug therapy;
- Modify, or discontinue medicinal drugs as outlined in the agreed upon patient-specific order or preapproved treatment protocol under the direction of a physician; and
- Administer medicinal drugs.

The bill defines a health care facility to expand the locations in which a consultant pharmacist services may be offered, to include:

- Ambulatory surgical center;
- Alcohol or chemical dependency treatment center;
- Inpatient hospice;
- Hospital;
- Ambulatory care center; or
- Nursing home or nursing home within a continuing care facility.

The bill prohibits a consultant pharmacist from modifying or discontinuing a medication if the consultant pharmacist does not have a written collaborative practice agreement with the consultant pharmacist; and clarifies that a consultant pharmacist is not authorized to diagnose any disease or condition.

The consultant pharmacist must maintain all drug, patient care and quality assurance records as required by current law; and, with the collaborating practitioner, must maintain written collaborative practice agreements that must be available upon request or during any department inspection.

The Board previously established, by rule, the additional training required for licensure as a consultant pharmacist under its general rulemaking authority.[33] The bill gives the Board express authority to establish additional education requirements for licensure as a consultant pharmacist.

The bill amends s. 381.0031, F.S., to require any licensed pharmacist authorized under a collaborative pharmacy practice agreement to perform or order and evaluate laboratory and clinical tests, to report immediately to the department any diagnoses or suspicions of a significant disease of public health.

The bill creates s. 465.1865, F.S., establishing a collaborative pharmacy practice for chronic health conditions authorizing provisions for pharmacists who are certified by the Board of

[33] *Supra* note 21.

Medicine to provide chronic health condition services under a collaborative pharmacy practice agreement. The chronic health conditions include the following:

- Arthritis;
- Asthma;
- Chronic obstructive pulmonary diseases;
- Type 2 diabetes;
- Human immunodeficiency virus or acquired immune deficiency syndrome; or
- Obesity.

To provide services under a collaborative pharmacy practice agreement, a pharmacist must be certified according to the following rules of the Board of Medicine that he or she:

- Holds an active and unencumbered license to practice pharmacy in the state;
- Has earned a degree of doctor of pharmacy or has completed five years of experience as a licensed pharmacist;
- Has completed an initial 20-hour course approved by the Board of Medicine in consultation with the Board of Osteopathic Medicine and the Board of Pharmacy which includes, at a minimum, instruction on all of the following:
  - Performance of patient assessments;
  - Ordering, performing, and interpreting clinical and laboratory tests related to collaborative pharmacy practice;
  - Evaluating and managing diseases and health conditions in collaboration with other health care practitioners; and
  - Any other area required by Board of Medicine rule, adopted in consultation with the Board of Osteopathic Medicine and the Board of Pharmacy.
- Maintains at least $250,000 of professional liability insurance coverage; and
- Has established a system to maintain records of all patients receiving services under a collaborative pharmacy practice agreement for a period of five years.

The terms and conditions of the collaborative pharmacy practice agreement must be appropriate to the pharmacist's education and training and the services delegated to the pharmacist must be within the collaborating physician's scope of practice. A copy of the pharmacist certification, as required according to the rules of the Board of Medicine, must be included as an attachment to the collaborative pharmacy practice agreement:

- A collaborative pharmacy practice agreement must include the following:
  - Name of the collaborating physician's patient or patients for whom a pharmacist may provide services;
  - Each chronic health condition to be collaboratively managed;
  - Specific medicinal drug or drugs to be managed by the pharmacist;
  - Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests;
  - Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur;
  - Beginning and ending dates for the collaborative pharmacy practice agreement and termination procedures; and
  - A statement that the collaborative pharmacy practice agreement may be terminated, in writing, by either party at any time.

A collaborative pharmacy practice agreement must be renewed at least every two years. The pharmacist, along with the collaborating physician, must maintain on file the collaborative pharmacy practice agreement at his or her practice location and must make such agreements available upon request or inspection. A pharmacist who enters into a collaborative pharmacy practice agreement must submit a copy of the signed agreement to the Board before the agreement may be implemented.

A pharmacist may not:

- Modify or discontinue medicinal drugs prescribed by a health care practitioner with whom her or she does not have a collaborative pharmacy practice agreement; or
- Enter into a collaborative pharmacy practice agreement while acting as an employee without the written approval of the owner of the pharmacy.

A physician may not delegate to a pharmacist the authority to initiate or prescribe a controlled substance as described in s. 893.03 or 21 U.S.C. s. 812, F.S.

In addition to the continuing education requirements under s. 465.009, a pharmacist who practices under a collaborative pharmacy practice agreement must, for each biennial licensure renewal, complete an eight hour continuing education course approved by the Board of Medicine in consultation with the Board of Osteopathic Medicine and the Board of Pharmacy which addresses issues related to the chronic conditions to be collaboratively managed. The pharmacist must submit confirmation of having completed the continuing education course when applying for licensure renewal. A pharmacist who fails to comply with these requirements is prohibited from practicing under a collaborative pharmacy practice agreement under this section.

The Board of Medicine in consultation with the Board of Osteopathic Medicine and the Board of Pharmacy must adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the collaborative pharmacy practice for chronic health conditions.

The bill provides an effective date of July 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

CS/CS/SB 1094 will require the department to incur non-recurring costs for rulemaking, which current resources are adequate to absorb.[34]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill is unclear as to where the written CPAs will be kept, and who, the consultant pharmacist or the collaborating practitioner, will be responsible for making them "available upon from the department or upon inspection by the department."

The bill expands the locations where a consultant pharmacist may practice, some of which are not inspected by the department, but by the Agency for Health Care Administrative (ACHA). The bill does not require the consultant pharmacist or the collaborating practitioner to make the CPA available to the AHCA upon request or inspection.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.0031, 465.003, and 465.0125.

The bill creates section 465.1865 of the Florida Statutes.

[34] Florida Department of Health fiscal analysis of SB 1094 (February 7, 2020)(on file with the Senate Appropriations Subcommittee on Health and Human Services).

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Appropriations on March 3, 2020:
The committee substitute:

- Adds provisions for consultant pharmacists who are certified by the Board of Medicine to provide chronic health condition services under a collaborative pharmacy practice agreement; and
- Requires a licensed pharmacist, authorized under a collaborative pharmacy practice agreement, to report any diagnoses or suspicions of the existence of a disease of public health significance immediately to the department.

CS by Health Policy on February 11, 2020:
The CS:

- Removes from the underlying bill's definition of the "practice of professional pharmacy" the ability to "initiate" medicinal drugs;
- Removes the ability of consultant pharmacists in the underlying bill to "initiate" medicinal drugs pursuant to a CPA with a physician, podiatrist, or dentist; and
- Requires the CPA be in writing.

B. Amendments:

None.